

### **REMARKS**

Applicants respectfully request the Examiner to reconsider the present application in view of the foregoing amendments to the claims and the following remarks.

#### ***Status of the Claims***

Claims 1-24 are currently pending in the present application. The Office Action is non-final. Claims 15 and 16 have been withdrawn from further consideration as directed to a non-elected invention. Claims 1-4, 7-8, and 10 are herein cancelled without prejudice or disclaimer. Claim 19 was previously cancelled. Claims 5, 6, 9, 11-14 and 17-18 have been amended without prejudice or disclaimer. No new matter has been added by way of amendment, because the amendments are supported by the present specification. The amendment to claim 9 further define and clarify the structure of the present invention. Support for amended claim 9 can be found at page 14, lines 18-23 and the bridging paragraph from page 14 to 15 of the present specification. Claims 20-24 are new. Support for claims 20-24 can be found in the original claims as well as on page 23, lines 3 to 17 of the present specification. Thus no new matter has been added.

Based upon the above considerations, entry of the present amendment is respectfully requested.

#### ***Issue Regarding Compliance with Sequence Rules***

The Examiner asserts that the present application is not compliant with the Sequence Rules. Applicants respectfully traverse. Applicants direct the Examiner to page 3, first

paragraph, of the Remarks section within the Preliminary Amendment dated November 18, 2005:

Also submitted herewith in full compliance with 37 C.F.R. §§1.821-1.825 is a disk copy of the Substitute Sequence Listing. The disk copy of the Sequence Listing, file "2005-11-10 0020-5363PUS1.txt," is identical to the paper copy, except that it lacks formatting.

Applicants respectfully request reconsideration regarding this issue and a statement from the Examiner that the application is compliant with the Sequence Rules.

#### ***Objections within the Specification***

The Examiner asserts that the specification was objected to due to informalities. Applicants respectfully traverse. In order to expedite prosecution, Applicants have amended the title and the specification. Applicants amended the specification to further clarify the amino acid sequences within the specification per the Examiner's suggestion.

Applicants respectfully request reconsideration and withdrawal of the present objection.

#### ***Claim Objections***

The Examiner asserts that claims 1-5 were objected to due to informalities. Claims 1-4 were cancelled, without prejudice and disclaimer, thus obviating the objection to these claims. Regarding claim 5, Applicants have amended the claim, per the Examiner's suggestion, to include definitions for the abbreviations "ADAMTS-13" and "VWF."

Applicants respectfully request reconsideration and withdrawal of the present objection.

***Rejection Under 35 U.S.C §112, First Paragraph, Written Description***

Claims 1-14 and 17-18 stand rejected under 35 U.S.C. §112, first paragraph, for failing to comply with the written description requirement (*See* pages 6 to 9 of the Office Action dated October 10, 2007; hereinafter "Office Action"). Claims 1-4, 7-8 and 10 have been cancelled herein without prejudice or disclaimer, thus obviating the rejection as to these claims. Applicants traverse the rejection as to the remaining claims as set forth herein.

Applicants have amended, without prejudice or disclaimer, the remaining claims to limit the substrate polypeptides to Asp<sup>1587</sup> to Arg<sup>1668</sup> and Asp<sup>1596</sup> to Arg<sup>1668</sup> of SEQ ID NO: 1. The substrate polypeptide Asp<sup>1587</sup> to Arg<sup>1668</sup> is SEQ ID NO:4, while the substrate polypeptide Asp<sup>1596</sup> to Arg<sup>1668</sup> is SEQ ID NO:5. The remaining claims are directed to these substrate polypeptides or a mutant substrate polypeptide for ADAMTS-13 which has an amino acid sequence identity of at least 90% or higher to the above substrate polypeptides. Further, Applicants note that in Figure 1 of the present application, cleavage of the polypeptides Asp<sup>1587</sup> to Arg<sup>1668</sup> and Asp<sup>1596</sup> to Arg<sup>1668</sup> of SEQ ID NO: 1 is clearly shown.

Applicants believe that the specification provides sufficient support to show that Applicants were in possession of the claimed subject matter at the time the present application was filed.

Therefore, in light of the amendments to remaining claims 5, 6, 9 11-14, and 17-18, reconsideration and withdrawal of the written description rejection is respectfully requested.

***Rejection Under 35 U.S.C §112, First Paragraph, Enablement***

Claims 1-14 and 17-18 stand rejected under 35 U.S.C. §112, first paragraph as failing to comply with the enablement requirement. The Examiner asserts that the claims contain subject matter not described in the specification in such a way as to enable one skilled in the art to make or use the invention. Claims 1-4, 7-8 and 10 have been cancelled herein without prejudice or disclaimer, thus obviating the rejection as to these claims. Applicants traverse the rejection as to the remaining claims as set forth herein.

Although Applicants do not agree that the claims lack enablement support in the specification, to expedite prosecution, remaining claims 5, 6, 9, 11-14 and 17-18 have been amended herein, without prejudice or disclaimer, to limit the substrate polypeptides to Asp<sup>1587</sup> to Arg<sup>1668</sup> and Asp<sup>1596</sup> to Arg<sup>1668</sup> of SEQ ID NO: 1 as mentioned in the previous rejection. Also, the remaining claims are directed to these substrate polypeptides or a mutant substrate polypeptide for ADAMTS-13 which has an amino acid sequence identity of at least 90% or higher to the above substrate polypeptides. Additionally, the mutant polypeptides which have been limited to those having an amino acid sequence identity of at least 90% or higher to the substrate polypeptides are further limited by the phrase “which retains the specificity to ADAMTS-13”. The Applicants believe that a skilled person in the art can easily practice the inventions relating to the mutant polypeptides as claimed.

There is ample support in the specification for the limitation “which retains the specificity to ADAMTS-13”. This can be found on page 14, lines 18-23. Additionally the amended term “identity” within claim 9 has support on the bridging paragraph from page 14 to page 15.

The Applicants submit that a skilled person in the art can easily practice the inventions relating to the mutant polypeptides as claimed. **Applicant herein provides a 37 C.F.R. § 1.132 Declaration** providing experiments that a person skilled in the art can easily practice the inventions relating to the mutant polypeptides as claimed. The experiment within the Declaration uses a mouse polypeptide which corresponds to a mutant polypeptide having different amino acid sequence from the human polypeptide Asp<sup>1596</sup>-Arg<sup>1668</sup>. The mouse polypeptide has an amino acid sequence identity of 86.3% (<90%) (10 amino acids are substituted) to the human polypeptide Asp<sup>1596</sup>-Arg<sup>1668</sup>.

Therefore, in light of the amendments and the enclosed Declaration, reconsideration and withdrawal of the enablement rejection of remaining claims 5, 6, 9, 11-14 and 17-18 are respectfully requested.

***Rejection Under 35 U.S.C. § 101, Non-Statutory Subject Matter***

Claims 1-10 stand rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. Claims 1-4, 7-8 and 10 have been cancelled herein without prejudice or disclaimer, thus obviating the rejection as to these claims. Applicants have amended claims 5, 6 and 9, without prejudice or disclaimer, to include the term "isolated" as per the Examiner's recommendation.

Applicant respectfully requests reconsideration and withdrawal of the present rejection.

***Rejection Under 35 U.S.C. § 102(b), Anticipation***

Claims 1-14 and 17-18 stand rejected under 35 U.S.C. § 102(b) as anticipated by Girma *et al.*, “Mapping of Distinct Von Willebrand Factor Domains Interacting Within Platelet GPIIb and GPIIb/IIIa and With Collagen Using Monoclonal Antibodies”, *Blood*, Vol. 67, No.5, pages 1356-1366, (1986) (hereinafter, “Girma *et al.*”). Claims 1-4, 7-8 and 10 have been cancelled herein without prejudice or disclaimer, thus obviating the rejection as to these claims. Applicants traverse the rejection as to the remaining claims as set forth herein.

The Examiner asserts that Girma *et al.* teach a purified human von Willebrand factor (VWF) and therefore the VWF of Girma *et al.* has the same identical amino acid sequence to SEQ ID No.: 1 of the present application.

Applicants have amended the claims without prejudice or disclaimer, to limit the scope of the present invention by limiting the claims to the substrate polypeptides Asp<sup>1587</sup> to Arg<sup>1668</sup> and Asp<sup>1596</sup> to Arg<sup>1668</sup> of SEQ ID NO: 1. Therefore the claimed polypeptides neither include nor overlap those described in Girma *et al.*

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). “When a claim covers several structures or compositions, either generically or as alternatives, the claim is deemed anticipated if any of the structures or compositions within the scope of the claim is known in the prior art.” *Brown v. 3M*, 265 F.3d 1349, 1351, 60 USPQ2d 1375, 1376 (Fed. Cir. 2001) “The identical invention must be shown in as complete detail as is contained in the ... claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir.

1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

Therefore, Girma *et al.* is substantially different from the present invention wherein the claimed polypeptides neither include nor overlap those described in Girma *et al.*

Thus, because of the lack of disclosure of all features as instantly claimed, the rejection in view of Girma *et al.* is overcome.

Applicants respectfully request reconsideration and withdrawal of the anticipation rejection of claims 5, 6, 9, 11-14 and 17-18.

In view of the above amendment, Applicants believe the pending application is in condition for allowance.

**CONCLUSION**

In view of the above remarks, it is believed that claims are allowable.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Paul D. Pyla, Reg. No. 59, 228, at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

Dated:

Respectfully submitted,

By 

Gerald M. Murphy, Jr.

Registration No.: 28,977

BIRCH, STEWART, KOLASCH & BIRCH, LLP

8110 Gatehouse Road

Suite 100 East

P.O. Box 747

Falls Church, Virginia 22040-0747

(703) 205-8000

Attorney for Applicants

Attachment: 37 C.F.R. § 1.132 Declaration